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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(OAKLAND DIVISION)**

D.J., a minor, by and through his mother and
Guardian ad Litem Myesha Reynolds,

Plaintiff,

v.

Gerber Products Company; Nestle S.A; Beech-
Nut Nutrition Company; Hain Celestial Group,
Inc.; and Walmart, Inc.,

Defendants.

CASE NO.: 4:24-cv-01836

**COMPLAINT FOR DAMAGES
DEMAND FOR JURY TRIAL**

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INTRODUCTION

1. This case involves a couple of manufacturers/sellers—namely, Gerber Products Company, Nestle S.A., Beech-Nut Nutrition Company Inc, and Walmart, Inc. (“Defendants”)—that *knowingly* sold baby food products (“Baby Foods”) which contain dangerous levels of toxic heavy metals—lead, arsenic, and mercury (collectively “Toxic Heavy Metals”), which are known to be severe neurotoxins—and how such toxic exposures substantially contributed to Plaintiff developing lifelong brain injury. Plaintiff is a child who lives with debilitating brain injury, namely in the form of the neurodevelopmental disorder autism spectrum disorder (“ASD”) and related *sequelae* because, as an infant, he consumed poisonous Baby Foods manufactured and/or sold by these Defendants. This case seeks to hold the Defendants accountable for their reprehensible conduct and ensure they are punished for permanently affecting Plaintiff’s ability to live a fulfilling life.

2. That Defendants’ Baby Foods are laced with staggering amounts of Toxic Heavy Metals recently made headlines following research and a Congressional investigation. In February 2021, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform released a report containing shocking details of Defendants’ tainted Baby Foods based on the submission of internal test results and company documents. Specifically, the Subcommittee found that Defendants sell Baby Foods containing levels of heavy metals ranging from tens to hundreds of parts per billion (“ppb”),¹ far eclipsing domestic and international regulatory standards. With a chilling note the Subcommittee concluded that “[m]anufacturers *knowingly* sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever.”² (emphasis added). Indeed, following the Congressional findings and subsequent public uproar, one manufacturer, Beech-Nut,

¹ Ppb (or ppbm) is used to measure the concentration of a contaminant in soils, sediments, and water. 1 ppb equals 1 µg (microgram) of substance per kg of solid (µg/kg). For the average baby weighing approximately 3kg, the quantities of Toxic Heavy Metals found in Defendants’ Baby Foods, as explained below, pose significant health risks.

² Ex. 1, Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) (“Subcommittee Report”) at 59, available at: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>.

1 recalled one of its baby food product lines from the market, citing dangerous levels of arsenic in its
2 single grain rice cereal, and exited the rice cereal market altogether.³

3 3. The high levels of Toxic Heavy Metals found in Defendants' Baby Foods are, in part,
4 a function of the ingredients used by Defendants to manufacture their Baby Foods, the setting of
5 dangerously inflated internal limits which Defendants willingly flouted, disregard of regulatory
6 standards, and corporate policies which failed to test finished products before market distribution,
7 purchase by unknowing parents, and consumption by vulnerable infants.

8 4. Defendants' malicious recklessness and callous disregard for human life has wreaked
9 havoc on the health of countless vulnerable children, all so that Defendants could maximize profits
10 while deliberately misleading parents regarding the safety of their Baby Foods. Accordingly, this
11 lawsuit will not only ensure that Plaintiff is duly compensated for his tragic injuries and Defendants
12 punished, but that future generations are protected from the poisonous products that Defendants
13 pander as "food".

14 **PARTIES**

15 **I. Plaintiff**

16 5. Plaintiff is a citizen of California and no other state.

17 **II. Defendants**

18 6. Defendant Gerber Products Company ("Gerber") is a citizen of Michigan and Virginia
19 with its principal place of business located at 1812 N. Moore Street, Arlington, VA 22209. Gerber
20 sells Baby Foods under the brand name Gerber. Gerber organizes its products into broad categories of
21 "formula", "baby cereal", "baby food", "snacks", "meals & sides" "beverages" and "organic". At all
22 relevant times, Gerber has conducted business and derived substantial revenue from its
23 manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial
24 district.

25
26
27 ³ FDA, *Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single*
28 *Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment*, available at:
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beech-nut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and>

1 7. Defendant Nestle S.A. (“Nestle”) is a citizen of Switzerland, with its principal place of
2 business located at Avenue Nestle 55, 1800 Vevey, Switzerland. Nestle is a global food and beverage
3 company with more than 2,000 brands, and sells Baby Foods under its subsidiary, Gerber. At all
4 relevant times, Nestle has conducted business and derived substantial revenue through its subsidiary
5 company, by manufacturing, advertising, distributing, selling, and marketing Baby Foods within this
6 judicial district.

7 8. Defendant Beech-Nut Nutrition Company Inc. (“Beech”) is a citizen of Delaware and
8 New York with its principal place of business located at 1 Nutritious Pl., Amsterdam, NY 12010.
9 Beech produced and sells its baby food under the “Beach Nut” brand name and primarily produces
10 Baby Foods for infants 4+ months up to 12+ months and includes a variety of cereals, “jars,” and
11 “pouches” for these age groups. At all relevant times Beech’s Baby Food was sold nationwide,
12 including throughout this judicial district, and Beech has conducted business and derived substantial
13 revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods
14 within this judicial district.

15 9. Defendant Hain Celestial Group, Inc. (“Hain”) is a citizen of Delaware and New York
16 with its principal place of business located at 1111 Marcus Ave., Lake Success, NY 11042. Hain sells
17 Baby Foods under the brand name Earth’s Best Organics. Hain offers infant and baby formula and
18 foods as well as toddler foods covering products from “organic infant cereal” to “organic snacks for
19 toddlers and kids on the go”. At all relevant times, Hain has conducted business and derived
20 substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby
21 Foods within this judicial district.

22 10. Defendant Walmart, Inc. (“Walmart”) is a citizen of Delaware and Arkansas with its
23 principal place of business located at 702 S.W. 8th St. Bentonville, AK 72716. Walmart sells Baby
24 Foods under the brand name Parent’s Choice. Parent’s Choice offers a wide selection of baby foods
25 ranging from “sweet potatoes & corn” to “toddler cookies” and “yogurt bites.” At all relevant times,
26 Walmart has conducted business and derived substantial revenue from its manufacturing, advertising,
27 distributing, selling, and marketing of Baby Foods within this judicial district.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess of \$75,000, exclusive of interest and costs.

12. This Court has personal jurisdiction over Defendants insofar as Defendants are authorized and licensed to conduct business in the State of California, maintain and carry on systematic and continuous contacts in this judicial district, regularly transact business within this judicial district, and regularly avail themselves of the benefits of this judicial district.

13. Additionally, Defendants caused tortious injury by acts and omissions in this judicial district and caused tortious injury in this district by acts and omissions outside this district while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this judicial district.

14. Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

15. **Divisional Assignment:** Assignment to this Division is proper because Plaintiff consumed Defendants' Baby Food in the County of Contra Costa, California.

FACTUAL ALLEGATIONS

I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods

16. In October 2019, an alliance of nonprofit organizations, scientists and donors named "Happy Babies Bright Futures" ("HBBF"), dedicated to designing and implementing "outcomes-based programs to measurably reduce babies' exposures to toxic chemicals"⁴, published a report investigating the presence of Toxic Heavy Metals in baby foods.⁵ The HBBF Report tested 168 different baby foods sold on the U.S. market and concluded that "[n]inety-five percent of baby foods tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, cadmium and

⁴ <https://www.hbbf.org/solutions>.

⁵ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) ("HBBF Report"), available at: www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

mercury. All but nine of 168 baby foods contained at least one metal; most contained more than one.”⁶ Specifically, the HBBF report identified “puffs and other snacks made with rice flour”, “[t]eething biscuits and rice rusks”, “infant rice cereal”, “apple, pear, grape and other fruit juices”, and “carrots and sweet potatoes” manufactured by the Defendant Baby Food Companies as particularly high in Toxic Heavy Metals.⁷

17. The results of the HBBF report were consistent with that of the U.S. Food and Drug Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic Heavy Metals in 33 of 39 types of baby food tested.⁸ However, the HBBF reported that “[f]or 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts.”⁹ The HBBF’s findings were by no means an outlier. Eight months prior to publication of the HBBF report, a study conducted by scientists at the University of Miami and the Clean Label Project “examined lead...concentrations in a large convenience sample of US baby foods.”¹⁰ The study detected lead in 37% of samples.¹¹ This was consistent with findings by researchers examining baby food products in other parts of the world.

II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods Sparking National Outrage

18. On February 4, 2021, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, published a report detailing its findings that Toxic Heavy Metals—including lead, arsenic, and mercury—were present in “significant levels” in numerous commercial baby food products.¹² Four companies—Hain, Gerber, Nurture, and Beech-Nut—produced internal testing policies, test results for ingredients and finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded

⁶ *Id.* at 6.

⁷ *Id.* at 10-11

⁸ *Id.* at 6.

⁹ *Id.* at 6.

¹⁰ Gardener, et al., *Lead and cadmium contamination in a large sample of United States infant formulas and baby foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at: <https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub>.

¹¹ *Id.*

¹² *See generally* Subcommittee Rpt.

1 their internal testing limits. Three companies—Plum, Walmart, and Sprout—refused to cooperate.¹³

2 19. The Subcommittee reported that the data submitted by the companies unequivocally
3 revealed that a substantial number of Defendants’ finished products and/or ingredients used to
4 manufacture the Baby Foods are tainted with significant levels of Toxic Heavy Metals, namely lead,
5 arsenic, and mercury.¹⁴ And, where the Defendants did set internal limits for the amount of metals
6 they allowed in their foods, Defendants routinely flouted their own limits and sold foods that
7 consistently tested above their limits.

8 20. **Nestle/Gerber.** Nestle and Gerber used high-arsenic ingredients, using 67 batches of
9 rice flour that had tested over 90 ppb inorganic arsenic. Furthermore, Nestle and Gerber have
10 regularly sold Baby Food products testing over 100 ppb arsenic, at times reaching 116 ppb. In a
11 follow-up report in September 2021 focused on Nestle/Gerber’s infant rice cereals, Congress noted
12 that Nestle/Gerber’s rice cereal tested up to 116 ppb inorganic arsenic, and its average rice cereal
13 product contained 87.43 ppb inorganic arsenic.¹⁵ While another baby food manufacturer discussed in
14 the Congressional report (Beech-Nut) recalled some of its products and completely discontinued sales
15 of its rice cereal, Nestle/Gerber has never taken such actions to protect children. Moreover, upon
16 information and belief, Nestle/Gerber permitted as much as 300 ppb of arsenic in the rice flour
17 ingredient used to manufacture their U.S. Baby Foods, notwithstanding the fact that Nestle/Gerber
18 often implemented stricter standards for Baby Foods sold in other countries.

19 21. Nestle/Gerber’s Baby Foods are also contaminated with elevated levels of lead.
20 Nestle/Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients
21 containing over 20 ppb lead. Furthermore, upon information and belief, Nestle/Gerber has sold Baby
22 Food products testing at and/or above 50 ppb of lead. Indeed, upon information and belief,
23 Nestle/Gerber has historically permitted as much as 150 ppb of lead into their Baby Food products.
24 Although Nestle/Gerber was fully aware that it was very feasible—with achievability rate of 90%—

25
26 ¹³ Subcommittee Rpt. at 2.

27 ¹⁴ *Id.* at 2-3.

28 ¹⁵ Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods* (September 29, 2021) (“Second Congress Report”), available at: oversight.house.gov.

1 to source lower-lead ingredients, the Nestle/Gerber proceeded to use high-lead ingredients in its
 2 foods. Nestle/Gerber rarely tests for mercury in its baby foods. 16 This, notwithstanding the fact that
 3 mercury is known to contaminate ingredients such as rice and poses a severe risk to babies' brain
 4 development.

5 22. Moreover, compounding these troubling findings, upon information and belief,
 6 Nestle/Gerber has historically only tested certain ingredients of its Baby Food products and rarely
 7 tested the finished products consumed by babies. Upon information and belief, it was not until
 8 recently that Nestle/Gerber started to implement finished product testing on its infant rice cereals, but
 9 none of its other Baby Food products. And Nestle/Gerber regularly flouted their own internal metal
 10 limits. Upon information and belief, regulatory testing found that a portion of Nestle/Gerber's infant
 11 rice cereals tested above 100 ppb. Such a metal level presents a risk to the neurodevelopment of
 12 babies consuming the products. Notwithstanding, the products were never recalled, and Gerber
 13 continued to market these products to vulnerable babies.

14 23. **Beech-Nut.** Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic.
 15 Beech-Nut routinely used high-arsenic additives that tested over 300 ppb arsenic to address product
 16 characteristics such as "crumb softness." On June 8, 2021, four months following the Congressional
 17 findings, Beech-Nut issued a voluntary recall of its infant single grain rice cereal and exited the rice
 18 cereal market completely.¹⁷ In its recall, Beech-Nut confirmed that its products exceed regulatory
 19 arsenic limits.¹⁸ And, Beech-Nut used ingredients containing as much as 886.9 ppb lead, as well as
 20 483 products that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that
 21 contained over 20 ppb lead. In a follow-up report in September 2021 focused on Defendants Beech-
 22 Nut and Gerber's infant rice cereals, Congress noted that Beech-Nut rice cereal tested up to 125 ppb
 23

24
 25 ¹⁶ *Id.* at 2-4.

26 ¹⁷ FDA, *Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single*
 27 *Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment*, available at:
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beech-nut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and>.

28 ¹⁸ *Beech-Nut to stop selling baby rice cereal after finding high arsenic levels* (CNN, June 9, 2021),
 available at:
<https://www.cnn.com/2021/06/09/health/beech-nut-baby-food-recall-wellness/index.html>.

1 inorganic arsenic and averaged 85.47 ppb inorganic arsenic.¹⁹ Beech-Nut's practice of testing
 2 ingredients, rather than finished products, for toxic heavy metals appears to have contributed to its
 3 failure to detect the dangerous inorganic arsenic levels in its recalled products. Lastly, Beech-Nut
 4 does not even test for mercury in baby food.

5 24. **Hain (Earth's Best Organic).** Hain sold finished baby food products containing as
 6 much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished products.
 7 Documents show that Hain used ingredients testing as high as 309 ppb arsenic. Hain used ingredients
 8 containing as much as 352 ppb lead. Hain used many ingredients with high lead content, including 88
 9 that tested over 20 ppb lead and six that tested over 200 ppb lead. And, Hain does not even test for
 10 mercury in its baby food.²⁰ However, independent testing by HBBF of Hain's Baby Foods confirm
 11 that Hain's products contain as much as 2.4 ppb of mercury.²¹

12 25. **Walmart (Parent's Choice).** Although Walmart refused to cooperate with the
 13 Congressional investigation. Again, however, independent data confirms that Walmart's baby foods
 14 are similarly tainted. For example, the HBBF Report observed that Walmart's Parent's Choice brand
 15 products contain 66 ppb inorganic arsenic, 26.9 ppb lead, 26.1 ppb cadmium, and 2.05 ppb
 16 mercury.²² Moreover, Walmart did not require any of the manufacturers of its Parent's Choice brand
 17 of baby food products to test the ingredients or finished products for heavy metals; and restricted any
 18 testing to a limited number of products containing select ingredients such as fruit juices, leaving the
 19 vast majority of its product line untested for metals. In fact, based upon information and belief,
 20 instead of striving to drive down metal levels in its products, Walmart increased, five-fold, the
 21 amount of arsenic that it allowed in its brand baby food. Furthermore, upon information and belief,
 22 Plaintiff submits that Walmart's pattern and practice of failing to test ingredients, willingly flouting
 23 its own internal standards, and selling products notwithstanding internal acknowledgement of their
 24 high metal content, follows that of the other Defendants discussed in this Complaint, and discovery

25 _____
 26 ¹⁹ Ex. 2, Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and
 27 Reform U.S. House of Representatives, *New Disclosures Show Dangerous Levels of Toxic Heavy*
 28 *Metals in Even More Baby Foods* (September 29, 2021) ("Second Congress Report").

²⁰ *Id.* at 2-4.

²¹ See HBBF Rpt. at 19.

²² See HBBF Report at 21, 22, 25-27.

here will further flesh out the extent of Walmart’s culpable conduct.

26. The metal concentrations discussed above greatly surpass the limits allowed by U.S. regulatory agencies. There are no FDA regulations governing the presence of Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb inorganic arsenic in infant rice cereal and proposed (not yet final) limits for lead in certain baby food categories. To the extent such regulations exist, the quantities of Toxic Heavy Metals in Defendants’ Baby Foods far exceed any permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However, these limits were created in reference to adult exposure, not infants. Compared to these thresholds, the test results of the Defendants’ Baby Foods and their ingredients are multiple folds greater than the permitted metal levels.

27. As found by the Subcommittee, the Defendants have willfully sold—and continue to sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of Toxic Heavy Metals in their products.

III. Dangers of Toxic Heavy Metals to Babies and Children

28. According to the World Health Organization (“WHO”), Toxic Heavy Metals, specifically lead and arsenic pose a “major public health concern” for children.²³ The Occupational Safety and Health Administration (“OSHA”) has warned that these metals “may build up in biological systems and become a significant health hazard.”²⁴ Indeed, the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (“ATSDR”) ranks arsenic as number *one* among substances present in the environment that pose the most significant potential threat to human health, followed by lead (second), and mercury (third).

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²³ World Health Organization, *Children’s Health and the Environment WHO training Package for the Health Sector* (October 2011), available at: https://www.who.int/ceh/capacity/heavy_metals.pdf.

²⁴ OSHA, *Toxic Metals*, available at: <https://www.osha.gov/toxic-metals>.

29. The threat presented by Toxic Heavy Metals to children’s health is widely shared by the global scientific community. For example, the FDA has set an Interim Reference Level (“IRL”) of 2.2 micrograms/day for lead exposure through baby food products.²⁵ That is the amount of lead exposure above which the agency considers associated with adverse neurological effects in babies. None of the Defendant Baby Food Manufacturers have ever conducted any tests or analyses to determine whether exposure to lead from their baby food products would result in children having blood lead amounts of 2.2 micrograms/day. The FDA, in its guidance documents for inorganic arsenic and lead in baby food products has repeatedly acknowledged the dangers of heavy metals to the neurodevelopment of infants.

Even low lead exposure can harm children’s health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects...Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time...Even though no safe level of lead exposure has yet been identified for children’s health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead. In particular, FDA is focused on the potential for neurodevelopmental effects from lead exposure, as review of the scientific literature indicates that *such adverse effects of lead consistently occur at a blood lead level associated with FDA’s IRL for children.* (emphasis added).²⁶

30. As one recent study observed, “[t]he implications of heavy metals with regards to children’s health have been noted to be more severe compared to adults. The elements’ harmful consequences on children health include mental retardation, neurocognitive disorders, behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given to heavy metals because of their high toxicity potential, widespread use, and prevalence.”²⁷ Children and, even more so, babies have higher exposure to metals compared to adults because they consume

²⁵ FDA (January 2023) *Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance For Industry*, available at: <https://www.fda.gov/media/164684/download>.

²⁶ *Id.*

²⁷ Osman, et al., *Exposure routes and health effects of heavy metals on children*, 32 BIOMETALS 563–573 (2019), available at: <https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas>.

more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.²⁸ And, the mechanisms needed to metabolize and eliminate heavy metals are comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune systems than adults.²⁹ For example, liver pathways that in adulthood metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in other organs.³⁰ According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants.”³¹ Thus, “the major windows of developmental vulnerability occur during infancy and early childhood due to continuing brain development after birth.”³² In short, even small amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

31. Notably, none of the Defendants ever conducted any kind of risk assessments or analyses to determine whether exposure to their baby food products exposed children to lead amounts known to harm neurodevelopment. On information and belief, exposure to Defendants’ Baby Food products exposed Plaintiff to heavy metal concentrations known to result in brain injury.

32. Indeed, upon and information and belief, Gerber (through research conducted by its parent company’s own private research group Nestle Research Center in Switzerland) has been aware for over two decades that low levels of arsenic can harm children’s neurodevelopment. Indeed, in its 2019 letter to Congress, Nestle bragged that it has access to a network of 4,800 experts, including scientists and toxicologists. Notwithstanding this, neither Gerber nor Nestle conducted any kind of risk assessments or analyses to determine whether exposure to their baby food products exposed

²⁸ Stein, et al., *In harm’s way: toxic threats to child development*, 23 J DEV BEHAV PEDIATR.1 S13–S22 (2002).

²⁹ Gorini, et al., *The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism* 1 REV. J. AUTISM DEV. DISORD. 1, 354–372 (2014), available at: <https://link.springer.com/article/10.1007/s40489-014-0028-3>.

³⁰ Del Rio, et al., *A comparison of arsenic exposure in young children and home water arsenic in two rural West Texas communities* 17 BMC PUBLIC HEALTH 850 1-13 (2017), available at: <https://bmcpublihealth.biomedcentral.com/articles/10.1186/s12889-017-4808-4>.

³¹ Roni Caryn Rabin, *Some Baby Food May Contain Toxic Metals, U.S. Reports* (NY TIMES, Feb 4, 2021), available at: <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html>

³² Gorini, et al. *supra*.

children to lead amounts known to harm neurodevelopment until concerns regarding contaminated baby foods entered widespread public discourse in recent years.

A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with Brain Injury, i.e., Autism in Pediatric Populations

33. It is well-known that exposure to heavy metals in early life can cause brain injury at low levels of exposure. And one of the ways in which such brain injury can present in a child is in the form of the neurodevelopmental disorders ASD. As the U.S. Centers for Disease Control observed in its 2020 Toxicological Profile for Lead, at just ≤ 10 $\mu\text{g/dL}$: “The following neurobehavioral effects in children have been associated with [lead]: “Altered mood and behaviors that may contribute to learning deficits, including *attention deficits, hyperactivity, autistic behaviors, conduct disorders, and delinquency.*”³³ (emphasis added). Likewise, the NIH states: “prenatal and early childhood exposure to heavy metals...may be linked to autism spectrum disorder.”³⁴

34. Multiple studies, reviews, and meta-analyses conducted throughout various parts of the world over the last decade have consistently observed that early life exposure to heavy metals can cause brain injury and, specifically, brain injury which manifests as ASD.

35. For example, four meta-analyses published in 2014, 2017, 2019 and 2020, respectively, all observed a consistent association between exposure to arsenic and mercury and ASD in children; with the authors in all three studies recommending – based on the data – that exposure to such metals in children be reduced as much as possible, and one of the study authors specifically concluding that “Results of the current meta-analysis revealed that mercury is an important causal factor in the etiology of ASD.”³⁵

³³ ATSDR (2020) *Toxicological Profile for Lead*, available at: <https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf>.

³⁴ NIH, ASD & the Environment.

³⁵ Jafari, et al., *The association between mercury levels and autism spectrum disorders: A systematic review and meta-analysis* 44 J. TRACE. ELEMEN. IN MED. & BIOL. 289-297 (2017); Wang, et al., *Exposure to Inorganic Arsenic and Lead and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 21 CHEM RES. TOXICOL. 32, 1904-1919 (2019), available at: <https://pubmed.ncbi.nlm.nih.gov/31549506/>; Sulaiman, et al., *Exposure to Aluminum, Cadmium, and Mercury and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 33 Chem. Res. Toxicol. 11, 2699-2718 (2020), available at: <https://pubmed.ncbi.nlm.nih.gov/32990432/>; Yoshimasu, et al., *A meta-analysis of the evidence on the impact of prenatal and early infancy*

36. In a recent 2017 NIH-funded prospective observational study, the authors examined the risk of ASD outcome in twins based on their respective body burden of lead. The study concluded in no uncertain terms that “prenatal and early childhood disruption (excess or deficiency) of multiple metals during critical developmental windows is associated with ASD, and suggests a role for elemental dysregulation in the etiology of ASD.”³⁶

37. Similarly, a large, prospective study from 2016 in Korean school children observed that low levels of lead exposure in early life are associated with autism, the authors specifically concluding: “even low blood lead concentrations...are associated with more autistic behaviors..., underscoring the need for continued efforts to reduce lead exposure.”³⁷

38. Furthermore, repeated associations between early life metal exposure and ASD have also been observed during the pre-natal timeframe, lending further strength to the findings of post-natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors prospectively assessed the relationship between pre-natal metal exposure in various biomarkers and autism risk. The study concluded that “[r]esults from the present study show several associations between levels of metals and elements during gestation and ASD and ADHD in children. The most notable ones involved arsenic...mercury...and lead. Our results suggest that even population levels of these compounds may have negative impacts on neurodevelopment.”³⁸ Similarly, in a study by the research group assessing the New Hampshire Birth Cohort, the authors evaluated the neurotoxic effects of heavy metals during various stages of pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to late pregnancy may be neurodevelopmentally harmful.”³⁹

exposures to mercury on autism and attention deficit/hyperactivity disorder in the childhood, 44 NEURO TOXICOL. 121-131 (2014), available at: <https://pubmed.ncbi.nlm.nih.gov/24952233/>.

³⁶ Arora, et al., *Fetal and postnatal metal dysregulation in autism* NATURE COMM. 1-10 (2017), available at: <https://www.nature.com/articles/ncomms15493>.

³⁷ Kim, et al., *Low-Level lead Exposure and Autistic Behaviors in School-Age Children*, 53 NEUROTOXICOLOGY 193-200 (2016).

³⁸ Skogheim, et al. *Metal and essential element concentrations during pregnancy and associations with autism spectrum disorder and attention-deficit/ hyperactivity disorder in children* 152 1-14 (2021).

³⁹ Doherty, et al., *Periconceptional and prenatal exposure to metal mixtures in relation to behavioral development at 3 years of age* 4 ENVIRON. EPIDEMIOL. (2020).

39. Moreover, such results have been replicated in studies throughout the world, including China, Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric diagnoses of autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results of this study are consistent with numerous previous studies, supporting an important role for heavy metal exposure, particularly mercury, in the etiology of ASD.”⁴⁰ Indeed, a 2015 Egyptian study noted “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*, may play a causal role in autism.” (emphasis added).⁴¹

40. The fact that such results, and many more, have been observed in multiple studies, conducted by different researchers, at different times, in different parts of the world, in children of multiple ages, utilizing different study methods (prospective, case-control and cross-sectional epidemiological analyses) and measuring a variety of end-points (including hair, blood, and urine), strongly supports a causal relationship between exposure to Toxic Heavy Metals and the development of ASD in children.

IV. Defendants Knowingly Sold Baby Foods Containing Dangerous Levels of Toxic Heavy Metals and Knew or Should Have Known of the Risks of Such Exposures in Children

41. During the time that Defendants manufactured and sold Baby Foods in the United States, the weight of evidence showed that Defendants’ Baby Foods exposed babies and children to unsafe levels of Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.

⁴⁰ Li, et al., *Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum Disorder*, 181 BIOL TRACE ELEM RES 31-37 (2018), available at: <https://pubmed.ncbi.nlm.nih.gov/28480499/>; Ryu, et al., *Associations of prenatal and early childhood mercury exposure with autistic behaviors at 5 years of age: The Mothers and Children's Environmental Health (MOCEH) study*, 15 SCI. TOTAL ENVIRON. 251-257 (2017), available at: <https://www.sciencedirect.com/science/article/abs/pii/S0048969717316479>; Dickerson, et al., *Autism spectrum disorder prevalence and associations with air concentrations of lead, mercury, and arsenic*, 188 ENVIRON MONIT. ASSESS. 407 (2016); Mohamed, et al., *Assessment of Hair Aluminum, Lead, and Mercury in a Sample of Autistic Egyptian Children: Environmental Risk Factors of Heavy Metals in Autism* BEHAV. NEUROL. (2015), available at: <https://pubmed.ncbi.nlm.nih.gov/26508811/>; Adams, et al., *Toxicological Status of Children with Autism vs. Neurotypical Children and the Association with Autism Severity*, 151 BIOL. TRACE ELEM. RES 171-180 (2013), available at: <https://pubmed.ncbi.nlm.nih.gov/23192845/>.

⁴¹ Mohamed, et al.

42. As discussed above, both independent testing, the Defendants' internal evaluations of their Baby Foods, and the Defendants' representations and disclosures to the Subcommittee and FDA reveal the presence of substantial amounts of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or should have known that their Baby Foods contain dangerous of Toxic Heavy Metals.

43. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of such Toxic Heavy Metals in Baby Food products on the U.S. market,⁴² and the HBBF Report further confirmed such contamination of Defendants' Baby Foods.⁴³ And, as the Subcommittee found, the Defendants continued to sell their Baby Foods even after testing of both ingredients and finished products revealed the presence of substantial amounts of Toxic Heavy Metals.⁴⁴

44. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly as it relates to adverse effects on the neurodevelopment of children—have been well known for decades. Defendants, as manufacturers and retailers of Baby Foods, are held to the standard of experts responsible for keeping abreast of the latest scientific developments related to the dangers of contaminants in their products. Furthermore, as alleged in more detail below, the Retailer Defendant is strictly liable for selling the Baby Foods which caused Plaintiff's harm. Defendants failed to take action in protecting vulnerable children from exposure to the Toxic Heavy Metals in their foods and, thus, subjected them to the risk of brain injury which can manifest as neurodevelopmental disorders such as ASD and related *sequelae*.

45. To be clear, the Defendants are able to manufacture Baby Foods that do not pose such a dangerous risk to the health of infants and children by using alternative ingredients, not adding certain pre-mix minerals and vitamins high in Toxic Heavy Metals, or sampling their ingredients from other sources. At the very least, Defendants were under a duty to warn unsuspecting parents of the presence of Toxic Heavy Metals in their Baby Foods. However, Defendants took no action, continued to sell their products with full knowledge of the risks posed by their Baby Foods, and misled consumers regarding the safety of their products, all to the harm of children.

⁴² See Gardener, et al., *supra*.

⁴³ See HBBF Report, *supra*.

⁴⁴ See, e.g., Subcommittee Report at 13-14.

V. Exemplary / Punitive Damages Allegations

46. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants' conduct is particularly reprehensible given that their toxic foods were directed at vulnerable babies—a population group far more susceptible than adults to the neurotoxic dangers of heavy metals.

47. Defendants were fully aware of the safety risks of Baby Foods, particularly the dangerous potential of their Baby Foods given the high content of Toxic Heavy Metals that have all been associated with brain injury in children. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers. Indeed, Defendants repeatedly market their Baby Foods as safe for consumption and go so far as claiming that they adhere to “the strictest standards in the world”; and provide “baby’s food full of nutrition while meeting standards strict enough for tiny tummies” as well as other statements and representations that hold out their Baby Foods as safe for consumption by infants. In actual fact, as discussed above, Defendants routinely sold Baby Foods containing astronomical amounts of Toxic Heavy Metals, regularly flouted their own internal limits of Toxic Heavy Metals in Baby Foods and failed to disclose to consumers that their products contained such dangerous contaminants.

48. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that their Baby Foods were harmless to humans, and that full disclosure of the true risks of the Toxic Heavy Metals present in the Baby Foods would limit the amount of money Defendants would make selling the products. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, failure to test, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Parents were denied the right to make an informed decision about whether to purchase and Defendants' Baby Food for their children, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

49. Accordingly, Plaintiff requests punitive damages against the Defendants for the harms caused to Plaintiff.

PLAINTIFF-SPECIFIC ALLEGATIONS

50. Plaintiff was diagnosed with ASD at approximately 1 and a half years of age.

51. Plaintiff started consuming Baby Food products manufactured and/or sold by the Defendants in approximately 2017 and consumed Defendants' Baby Food products at various times through early childhood.

52. Upon information and belief, the Baby Food products manufactured/marketed by Defendants and consumed by Plaintiff were all contaminated with substantial quantities of Toxic Heavy Metals, namely lead, arsenic, and mercury – exceeding that of any regulatory limits.

53. Upon information and belief, as a direct and proximate result of consuming Defendants' Baby Foods, Plaintiff was exposed to substantial quantities of Toxic Heavy Metals, namely lead, arsenic, and mercury.

54. As a direct and proximate result of consuming Defendants' Baby Foods and the exposure to the Toxic Heavy Metals therein – Plaintiff suffered brain injury which manifested as ASD and related *sequelae*.

55. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the levels contained in Defendants' Baby Foods can cause brain injury which can manifest as the neurodevelopmental disorders ASD and related *sequelae* in humans.

56. Had any Defendant warned Plaintiff's carers that Defendants' Baby Foods could lead to exposure to Toxic Heavy Metals or, in turn, brain injury, Plaintiff would not have consumed the Baby Foods.

57. Plaintiff alleges that as a direct and proximate result of Plaintiff's consumption of Baby Foods supplied and distributed by Defendants, Plaintiff suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to brain injury which manifested as ASD and related *sequelae*.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

58. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

1 59. At all relevant times, Defendants engaged in the business of researching, testing,
2 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
3 promoting Baby Foods, which are defective and unreasonably dangerous to consumers, including
4 Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous
5 characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate
6 control and supervision of Defendants. At all relevant times, Defendants registered, researched,
7 manufactured, distributed, marketed, and sold Baby Foods and aimed at a consumer market.

8 60. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,
9 sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their
10 Baby Foods, and in the course of same, directly advertised or marketed the products to consumers
11 and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the
12 consumption of Baby Foods.

13 61. At all relevant times, Defendants had a duty to properly test, develop, design,
14 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide
15 proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and
16 consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to
17 warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or
18 distributor of food, are held to the knowledge of an expert in the field.

19 62. At the time of manufacture, Defendants could have provided the warnings or
20 instructions regarding the full and complete risks of Baby Foods because they knew or should have
21 known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

22 63. At all relevant times, Defendants failed and deliberately refused to investigate, study,
23 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
24 those who would foreseeably use or be harmed by Defendants' Baby Foods.

25 64. Even though Defendants knew or should have known that Baby Foods posed a grave
26 risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with
27 use and exposure to the products. The dangerous propensities of their products and the neurotoxic
28 characteristic of Toxic Heavy Metals contained in Defendants' Baby Foods, as described above, were

1 known to Defendants, or scientifically knowable to Defendants through appropriate research and
2 testing by known methods, at the time they distributed, supplied or sold the product, and were not
3 known to end users and consumers, such as Plaintiff. The product warnings for Baby Foods in effect
4 during the time period Plaintiff consumed Baby Foods were vague, incomplete or otherwise
5 inadequate, both substantively and graphically, to alert consumers to the severe health risks
6 associated with Baby Foods consumption.

7 65. Defendants knew or should have known that their products created significant risks of
8 serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or
9 instruct consumers, i.e., the reasonably foreseeable users, of the risks of exposure to their products.
10 Defendants failed to warn and have wrongfully concealed information concerning the dangerous
11 level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to
12 expose children to Toxic Heavy Metals, and further, have made false and/or misleading statements
13 concerning the safety of Baby Foods.

14 66. At all relevant times, Defendants' Baby Foods reached the intended consumers,
15 handlers, and users or other persons coming into contact with these products, including Plaintiff,
16 without substantial change in their condition as designed, manufactured, sold, distributed, labeled,
17 and marketed by Defendants.

18 67. Plaintiff was exposed to Defendants' Baby Foods without knowledge of their
19 dangerous characteristics.

20 68. At all relevant times, Plaintiff was exposed to Defendants' Baby Foods while using
21 them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous
22 characteristics.

23 69. Plaintiff could not have reasonably discovered the defects and risks associated with
24 Baby Foods prior to or at the time of Plaintiff consuming Baby Foods. Plaintiff relied upon the skill,
25 superior knowledge, and judgment of Defendants to know about and disclose serious health risks
26 associated with using Defendants' products.

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1 70. Defendants knew or should have known that the information disseminated with their
2 Baby Foods were inadequate, failed to communicate adequate information on the dangers of
3 consumption, and failed to communicate warnings and instructions that were appropriate and
4 adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

5 71. The information that Defendants did provide or communicate failed to contain
6 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
7 avoid consuming the products. Instead, Defendants disseminated information that was inaccurate,
8 false, and misleading, and which failed to communicate accurately or adequately the comparative
9 severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods;
10 continued to aggressively promote the safety of their products, even after they knew or should have
11 known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise
12 suppressed, through aggressive marketing and promotion, any information or research about the risks
13 and dangers of consuming Baby Foods.

14 72. This alleged failure to warn is not limited to the information contained on Baby Foods
15 labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by
16 disclosing the known risks associated with Baby Foods through other non-labeling mediums, *i.e.*,
17 promotion, advertisements, public service announcements, and/or public information sources. But
18 the Defendants did not disclose these known risks through any medium. The ability to provide such
19 warnings is not prohibited by any federal law.

20 73. Furthermore, Defendants possess a First Amendment Right to make truthful
21 statements about the products they sell, and no law could lawfully restrict that constitutional right.

22 74. Had Defendants provided adequate warnings and instructions and properly disclosed
23 and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of
24 developing injuries and could have obtained or used alternative products. However, as a result of
25 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted
26 his injuries.

27 75. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
28 babies and children, including Plaintiff, with knowledge of the safety problems associated with Baby

1 Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions
2 not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an
3 award of punitive damages.

4 76. The Defendants' lack of adequate warnings and instructions accompanying their Baby
5 Foods were a substantial factor in causing Plaintiff's injuries.

6 77. As a direct and proximate result of the Defendants' failure to provide an adequate
7 warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
8 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
9 not limited to past and future medical expenses, lost income, and other damages.

10 78. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in
11 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
12 other and further relief as this Court deems just and proper.

13 **COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

14 79. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
15 if fully stated herein.

16 80. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
17 sold, handled, and distributed the Baby Foods consumed by Plaintiff. These actions were under the
18 ultimate control and supervision of Defendants.

19 81. At all relevant times, Defendants' Baby Food products were manufactured, designed,
20 and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by
21 or exposure to infants and babies, including Plaintiff.

22 82. Defendants' Baby Food products as researched, tested, developed, designed, licensed,
23 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
24 design and formulation in that, when they were placed into the stream of commerce, they were
25 unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would
26 contemplate.

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1 83. Defendants' Baby Food products, as researched, tested, developed, designed, licensed,
2 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
3 design and formulation in that, when they left the hands of Defendants', the foreseeable risks
4 exceeded the alleged benefits associated with their design and formulation.

5 84. At all relevant times, the Baby Food products consumed by Plaintiff was expected to
6 and did reach Plaintiff without a substantial change in its condition as manufactured, handled,
7 distributed, and sold by Defendants.

8 85. At all relevant times, Defendants knew or had reason to know that their Baby Food
9 products were defective and were inherently dangerous and unsafe when used in the manner
10 instructed and provided by Defendants.

11 86. Therefore, at all relevant times, Defendants' Baby Food products, as researched,
12 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold
13 and marketed by Defendants were defective in design and formulation, in one or more of the
14 following ways:

15 When placed in the stream of commerce, Defendants' Baby Food products were unreasonably
16 dangerous in that they were hazardous and posed a grave risk of causing brain injury that manifests as
17 the neurodevelopmental disorders ASD and related *sequelae* when used in a reasonably anticipated
18 manner due to the substantial quantities of Toxic Heavy Metals in the Baby Foods; When placed in
19 the stream of commerce, Defendants' Baby Food products contained unreasonably dangerous design
20 defects and were not reasonably safe when used in a reasonably anticipated or intended manner;
21 Defendants did not sufficiently test, investigate, or study their Baby Food products; Exposure to the
22 Toxic Heavy Metals in Defendants' Baby Food products present a risk of harmful effects that
23 outweigh any potential utility stemming from their use; Defendants knew or should have known at
24 the time of marketing Baby Food products that exposure to their Baby Food products could result in
25 brain injury that manifests as ASD and related *sequelae* in children; Defendants did not conduct
26 adequate post-marketing surveillance of their Baby Food products; and Defendants could have
27 employed safer alternative designs and formulations.

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1 87. Plaintiff consumed Defendants' Baby Food products in an intended or reasonably
2 foreseeable manner without knowledge of their dangerous characteristics.

3 88. Defendants' Baby Food products were and are more dangerous than alternative
4 products, and Defendants could have designed their Baby Food products to avoid harm to children.
5 Indeed, at the time Defendants designed the Baby Food products, the state of the industry's scientific
6 knowledge was such that a less risky design or formulation was attainable.

7 89. At the time the Baby Food products left Defendants' control, there was a practical,
8 technically feasible and safer alternative design that would have prevented the harm without
9 substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods.

10 90. Defendants have intentionally and recklessly defectively designed the Baby Foods
11 with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing
12 their economic interests above the health and safety of the Plaintiff.

13 91. The design defects in Defendants' Baby Foods were substantial factors in causing
14 Plaintiff's injuries.

15 92. As a direct and proximate result of the Defendants' defective design of the Baby
16 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
17 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to
18 medical expenses, lost income, and other damages.

19 **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's
20 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
21 further relief as this Court deems just and proper.

22 **COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

23 93. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
24 if fully stated herein.

25 94. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
26 sold, handled, and distributed the Baby Foods consumed by Plaintiff.

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1 95. At all relevant times, the Baby Foods consumed by Plaintiff was expected to and did
2 reach Plaintiff without a substantial change in its condition as manufactured, handled, distributed, and
3 sold by Defendants.

4 96. At all relevant times, the Baby Foods consumed by Plaintiff was used in a manner that
5 was foreseeable and intended by Defendants.

6 97. The Baby Foods consumed by Plaintiff was not reasonably safe for their intended use
7 and were defective with respect to their manufacture, as described herein, in that Defendants deviated
8 materially from their design and manufacturing specifications and/or such design and manufacture
9 posed an unreasonable risk of harm to Plaintiff.

10 98. The Defendants' Baby Foods are inherently dangerous and defective, unfit and unsafe
11 for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of
12 parents or children.

13 99. The Baby Foods create risks to the health and safety of babies that are far more
14 significant and devastating than the risks posed by other baby food products, and which far outweigh
15 the utility of the Baby Foods products because of Defendants' manufacturing defects, which included
16 but were not limited to: Failure to adequately inspect/test the Baby Foods during the manufacturing
17 process; Failure to implement procedures that would reduce or eliminate the levels of Toxic Heavy
18 Metals in Baby Foods; Failure to avoid using ingredients free from, or which contain far less, Toxic
19 Heavy Metals to manufacture Baby Foods.

20 100. Defendants have intentionally and recklessly manufactured the Baby Foods with
21 wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their
22 economic interests above the health and safety of the Plaintiff.

23 101. The manufacturing defects in Defendants' Baby Foods were substantial factors in
24 causing Plaintiff's injuries.

25 102. As a direct and proximate result of the Defendants' defective manufacture of the Baby
26 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
27 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to
28 medical expenses, lost income, and other damages.

1 **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's
2 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
3 further relief as this Court deems just and proper.

4 **COUNT IV: NEGLIGENCE – FAILURE TO WARN**

5 103. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
6 if fully stated herein.

7 104. At all relevant times, Defendants engaged in the business of testing, developing,
8 designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods. Defendants
9 knew or by the exercise of reasonable care should have known that their Baby Foods are not
10 accompanied with adequate warnings concerning the dangerous characteristics of Baby Foods and
11 Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants.

12 105. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,
13 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Baby
14 Foods, and in the course of same, directly advertised or marketed the products to consumers and end
15 users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of
16 Baby Foods.

17 106. At all relevant times, Defendants had a duty to properly test, develop, design,
18 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide
19 proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and
20 consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to
21 warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or
22 distributor of food products, are held to the knowledge of an expert in the field.

23 107. At the time of manufacture, Defendants could have provided warnings regarding the
24 full and complete risks of Baby Foods and Toxic Heavy Metals because they knew or should have
25 known use of Baby Foods was dangerous, harmful and injurious when used by Plaintiff in a
26 reasonably foreseeable manner.

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1 108. At all relevant times, Defendants failed and deliberately refused to investigate, study,
2 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
3 those who would foreseeably use or be harmed by Defendants' Baby Foods.

4 109. Defendants knew or should have known that Baby Foods posed a grave risk of harm,
5 but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure
6 to the products. The dangerous propensities of their products and the characteristics of Toxic Heavy
7 Metals contained in substantial amounts in their Baby Foods, as described above, were known to
8 Defendants, or scientifically knowable to Defendants through appropriate research and testing by
9 known methods, at the time they distributed, supplied or sold the product, and were not known to end
10 users and consumers, such as the Plaintiff.

11 110. Defendants further breached their duty by failing to use reasonable care to adequately
12 warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their
13 products. Defendants failed to warn and have wrongfully concealed information concerning the
14 dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby
15 Foods to expose babies and toddlers to Toxic Heavy Metals, and further, have made false and/or
16 misleading statements concerning the safety of Baby Foods.

17 111. At all relevant times, Plaintiff was exposed to excessive levels of Toxic Heavy Metals
18 through consumption of Toxic Heavy Metals while using them for their intended or reasonably
19 foreseeable purposes, without knowledge of their dangerous characteristics.

20 112. Defendants knew or should have known that the minimal warnings disseminated with
21 their Baby Foods were inadequate, failed to communicate adequate information on the dangers and
22 safe use/exposure, and failed to communicate warnings and instructions that were appropriate and
23 adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

24 113. The information that Defendants did provide or communicate failed to contain
25 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
26 avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and
27 misleading, and which failed to communicate accurately or adequately the comparative severity,
28 duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to

1 aggressively promote the efficacy of their products, even after they knew or should have known of
2 the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed,
3 through aggressive marketing and promotion, any information or research about the risks and dangers
4 of consuming Baby Foods.

5 114. A reasonable company under the same or similar circumstance would have warned
6 and instructed of the dangers of Baby Foods and Toxic Heavy Metals contained therein.

7 115. This alleged failure to warn is not limited to the information contained on the labeling
8 of Defendants' Baby Foods. Defendants were able, in accord with federal law, to comply with
9 relevant state law by disclosing the known risks associated with Baby Foods and Toxic Heavy Metals
10 through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements,
11 and/or public information sources. But the Defendants did not disclose these known risks through
12 any medium.

13 116. Furthermore, Defendants possess a First Amendment Right to make truthful
14 statements about the products they sell, and no law could lawfully restrict that constitutional right.

15 117. Had Defendants provided adequate warnings and instructions and properly disclosed
16 and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of
17 developing injuries and could have obtained or used alternative products. However, as a result of
18 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted
19 his injuries.

20 118. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
21 consumers and users of their products, including Plaintiff, with knowledge of the safety problems
22 associated with Baby Foods, and suppressed this knowledge from the general public. Defendants
23 made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants'
24 reckless conduct warrants an award of punitive damages.

25 119. The Defendants' lack of adequate warnings and instructions accompanying their Baby
26 Foods were a substantial factor in causing Plaintiff's injuries.

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120. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

121. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT V: NEGLIGENT PRODUCT DESIGN

122. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby Foods.

123. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.

124. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods because the product exposed users to unsafe levels of Toxic Heavy Metals.

125. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing the Baby Foods with ingredients and/or components high in Toxic Heavy Metals.

126. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing and formulation, in one or more of the following ways:

When placed in the stream of commerce, Defendants' Baby Foods were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

When placed in the stream of commerce, Defendants' Baby Foods were unreasonably dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated manner;

When placed in the stream of commerce, Defendants' Baby Foods contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or

1 intended manner;

2 Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically,
3 the content of Toxic Heavy Metals in the ingredients used to manufacture the foods and/or the
4 finished products;

5 Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically,
6 the ability for Baby Foods to expose babies to high amounts of Toxic Heavy Metals;

7 Exposure to Baby Foods presents a risk of harmful effects that outweigh any potential utility
8 stemming from the use of the products;

9 Defendants knew or should have known at the time of marketing Baby Foods that exposure to
10 Toxic Heavy Metals contained in the Baby Foods could result in brain injury that manifests as ASD
11 and other severe illnesses and injuries;

12 a. Defendants did not conduct adequate post-marketing surveillance of their Baby
13 Foods; and

14 b. Defendants could have employed safer alternative designs and formulations.

15 For example, the Defendants could have avoided use of certain ingredients
16 high in Toxic Heavy Metals, avoided using pre-mix vitamins high in Toxic
17 Heavy Metals, and/or sampled their ingredients from other sources.

18 127. The Defendants breached their duty by failing to use reasonable care by failing to use
19 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and
20 safer alternative design that would have prevented the harm without substantially impairing the
21 reasonably anticipated or intended function of Defendants' Baby Foods.

22 128. A reasonable company under the same or similar circumstances would have designed
23 a safer product.

24 129. Plaintiff was harmed directly and proximately by the Defendants' failure to use
25 reasonable care in the design of their Baby Foods. Such harm includes significant exposure to a Toxic
26 Heavy Metals, which can cause or contribute to brain injury that manifests as ASD and related
27 *sequalae*.

1 130. Defendants' defective design of Baby Foods was willful, wanton, malicious, and
2 conducted with reckless disregard for the health and safety of consumers of the Baby Foods,
3 including Plaintiff.

4 131. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's
5 injuries.

6 132. As a direct and proximate result of the Defendants' defective design of the Baby
7 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
8 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past
9 and future medical expenses, lost income, and other damages.

10 133. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in
11 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
12 other and further relief as this Court deems just and proper.

13 **COUNT VI: NEGLIGENT MANUFACTURING**

14 134. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
15 if fully stated herein.

16 135. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
17 distributed the Baby Foods that Plaintiff consumed.

18 136. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing,
19 marketing, sale, and distribution of Baby Foods.

20 137. The Defendants knew or, by the exercise of reasonable care, should have known, use
21 of Baby Foods were carelessly manufactured, dangerous, harmful and injurious when used by
22 Plaintiff in a reasonably foreseeable manner.

23 138. The Defendants knew or, by the exercise of reasonable care, should have known,
24 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby
25 Foods improperly manufactured, tested, marketed, distributed, and sold.

26 139. Without limitation, examples of the manner in which Defendants breached their duty
27 to exercise reasonable care in manufacturing Baby Foods, included:

28 a. Failure to adequately inspect/test the Baby Foods during the manufacturing

process;

b. Failure to implement procedures that would reduce or eliminate levels of Toxic Heavy Metals in Baby Foods; and

c. Failure to avoid using ingredients free from, or which contain far less, Toxic Heavy Metals to manufacture Baby Foods.

140. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality and safety of their product.

141. Plaintiff was harmed directly and proximately by the Defendants' failure to use reasonable care in the manufacture of their Baby Foods. Such harm includes significant exposure to a Toxic Heavy Metals, which can cause or contribute to brain injury which manifests as ASD and related *sequelae*.

142. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Baby Foods, including Plaintiff.

143. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's injuries.

144. As a direct and proximate result of the Defendants' improper manufacturing of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

145. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

146. Plaintiff demands a trial by jury on all the triable issues within this pleading.

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PRAYER FOR RELIEF

147. WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against the Defendants for:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;
- c. pre-judgment and post-judgment interest;
- d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and
- e. any other relief the Court may deem just and proper.

Dated: March 22, 2024

/s/ Sara Beth Craig

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